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EXAMINER	
KAUR, GURPREET	
ART UNIT	PAPER NUMBER
1795	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,504	PAULUS, CHRISTIAN	
	Examiner	Art Unit	
	GURPREET KAUR	1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *9/8/09*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Claims

1. Claims 13-32 are pending in this application.

Claim Objections

2. Applicant's amendment to claim 19 is accepted.

Response to Amendment

Applicant's amendment of 9/08/2009 does not render the application allowable.

Status of the Rejection

3. Rejections under 35 USC 102(b) and 35 USC 103(a) from previous office action are maintained.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Madou et al. (U.S. Pat. No. 4,874,500).

Regarding claim 29, Madou et al. teaches a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);

an integrated reference electrode (reference electrode) in (connected) the integrated circuit (48) on the substrate (see figure 1);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2) and surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2);

composite membrane such as enzyme based membrane can also be disposed in the well (see col. 7, lines 31-34), therefore sensor array (see figure 9) includes biological molecules (enzyme based membrane);

electrically coupling (connecting) the integrated circuit (48) to the core of the integrated reference electrode (see col. 12, lines 50-53 and figure 4 and 7).

Claim 29 is/are considered product-by-process claim wherein the reference electrodes is made by printing silver as metal on the substrate. The cited prior art teaches all of the positively recited structure of the claimed apparatus or product. The determination of patentability is based upon the apparatus structure itself. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 13 and 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claim 13, Madou et al. teaches a method for producing a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2);

surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2)

electrically coupling (connecting) the integrated circuit (48) to the core (silver layer) of the integrated reference electrode (see col. 12, lines 50-53 and figures 4 and 7).

Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34) which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the applying biological molecules by printing on the sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

However, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the sensing cell (active electrode) (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50).

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

6. Regarding claims 16 and 17, Madou et al. teaches that silver chloride is the salt of the metal (silver) which is produced by chlorinating the core made up of silver by chemical method (see col. 18, lines 18-29).

7. Regarding claim 18, Madou et al. indicates that the integrated circuit (48) is configured in a manner such that it process signals generated from the reference electrode (see col. 12, lines 23-26).

8. Regarding claim 19, Madou et al. teaches that the substrate (12) is made up of semiconductor material (see col. 4, lines 37-38).

9. Claims 14, 15 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548) as applied to claim 13 above, and further in view of Saito et al. (U.S. Pat. No. 6,021,339).

Regarding claim 14, Madou et al. teaches a coupling structure (palladium layer) is layered underneath the silver/silver chloride layer for formation of the reference electrode and the conductor is used to electrically couple the integrated circuit (48) with the reference electrode which comprises the silver core. (see col. 18, lines 18-24, col.12, lines 49-51 and figures 6 and 7).

Madou et al. does not indicate that the coupling structure is used to electrically couple the integrated circuit with core of the reference electrode.

However, Saito et al. teaches a sensor wherein the reference electrode is made by layering the coupling structure (titanium and platinum layer) underneath the core (silver layer) on the substrate and a lead is also formed on the same substrate to connect the reference electrode to current detecting circuit (see col. 7, lines 14-19 and figures 4A-C and 6). Saito et al. indicates that coupling structure (titanium and platinum layers) are formed for improved contactivity (see col. 7, lines 17-18), therefore it would be obvious that coupling structure (titanium and platinum layers) is used to couple the core (silver layer) with the current detecting circuit.

Therefore it would have been obvious to person of ordinary skill in the art at the time of invention to incorporate the coupling structure of the Saito et al. with the Madou et al. device to for improved contactivity between the reference electrode and the integrated circuit.

10. Regarding claim 15, Saito et al. teaches that the coupling structure (titanium and platinum layer) is underneath the core (silver layer) (see col. 7, lines 17-19), therefore the core (silver layer) covers the coupling structure.

11. Regarding claim 20, Saito et al. teaches that the coupling structure is formed from platinum (see col. 7, lines 17-18).

12. Claims 21 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Yoshikawa (English machine translation of JP 11238733,) and Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claim 21, Madou et al. teaches method for producing a biosensor circuit (see col. 12, lines 20-23) comprising:

forming an integrated circuit (48) in a substrate (12) (see col. 12, lines 20-23);

forming a core (silver layer) of an integrated reference electrode (reference electrode) by depositing silver material as metal on the substrate (12) (see col. 18, lines 16-29 and figure 2);

surrounding the core made up of silver material by a sheath (layer) made up of sparingly soluble salt of the silver (AgCl) to form integrated reference electrode (reference electrode) (see col. 18, lines 16-29, see col. 16, lines 42-44 and figure 2)

electrically coupling (connecting) the integrated circuit (48) to the core of the integrated reference electrode (see col. 12, lines 50-53 and figure 4 and 7).

Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34), which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the reference electrode is made by printing silver salt material on the substrate and chemically reducing the silver salt material to form silver and Madou et al. also does not teach about applying biological molecules by printing on sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

However, Yoshikawa et al. teaches method of making electronic device (see paragraph 001) wherein the silver layer (9a) is deposited by applying silver salt material (ammonia based silver nitrate) on the substrate (2) and chemically reducing the silver salt material to form silver (see paragraph 18). Yoshikawa et al. further indicates that such a method provides less heat to the substrate during formation of the silver layer (see paragraph 32)

Therefore it would be obvious to person of ordinary skill in the art at the time of the invention to incorporate the Yoshikawa et al. method of forming silver layer with the

Madou et al. method to impart less heat to substrate to prevent damage to the substrate.

Furthermore, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the active electrode (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50)

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

13. Regarding claims 24 and 25, Madou et al. teaches that silver chloride is the salt of the metal (silver) which is produced by chlorinating the core made up of silver by chemical method (see col. 18, lines 18-29).

14. Regarding claim 26, Madou et al. indicates that the integrated circuit (48) is configured in a manner such that it process signals generated from the reference electrode (see col. 12, lines 23-26).

15. Regarding claim 27, Madou et al. teaches that the substrate (12) is made up of semiconductor material (see col. 4, lines 37-38).

16. Claims 22, 23 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Yoshikawa (English machine translation of JP 11238733,) and Hill et al. (U.S. Pat. No. 5,727,548) as applied to claim 21 above, and further in view of Saito et al. (U.S. Pat. No. 6,021,339).

Regarding claim 22, Madou et al. teaches a coupling structure (palladium layer) is layered underneath the silver/silver chloride layer for formation of the reference electrode and the conductor is used to electrically couple the integrated circuit (48) with the reference electrode which comprises the silver core. (see col. 18, lines 18-24, col.12, lines 49-51 and figures 6 and 7).

Madou et al. does not indicate that the coupling structure is used to electrically couple the integrated circuit with core of the reference electrode.

However, Saito et al. teaches a sensor wherein the reference electrode is made by layering the coupling structure (titanium and platinum layer) underneath the core (silver layer) on the substrate and a lead is also formed on the same substrate to connect the reference electrode to current detecting circuit (see col. 7, lines 14-19 and figures 4A-C and 6). Saito et al. indicates that coupling structure (titanium and platinum layers) are formed for improved contactivity (see col. 7, lines 17-18), therefore it would be obvious that coupling structure (titanium and platinum layers) is used to couple the core (silver layer) with the current detecting circuit.

Therefore it would have been obvious to person of ordinary skill in the art at the time of invention to incorporate the coupling structure of the Saito et al. with the Madou et al. device to for improved contactivity between the reference electrode and the integrated circuit.

17. Regarding claim 23, Saito et al. teaches that the coupling structure (titanium and platinum layer) is underneath the core (silver layer) (see col. 7, lines 17-19), therefore the core (silver layer) covers the coupling structure.

18. Regarding claim 28, Saito et al. teaches that the coupling structure is formed from platinum (see col. 7, lines 17-18).

19. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Madou et al. (U.S. Pat. No. 4,874,500) in view of Hill et al. (U.S. Pat. No. 5,727,548).

Regarding claims 30-32, Madou et al. also indicates that the composite membrane; such as an enzyme based membrane, can also be disposed in the well (see col. 7, lines 31-34), which is comprised of electrodes. Furthermore, Madou et al. teaches that the array of sensing cells (working electrode) can be provided on the substrate (see col. 13, lines 232-35).

Madou et al. does not teach that the applying biological molecules by printing on sensor array and effecting the printing of silver material on the substrate and printing of the biological molecules on the sensor array in the same work step.

However, Hill et al. teaches a method of producing a device comprising electrodes and permanent circuitry components wherein the biological molecules (enzyme containing layer 43) are screen printed on the active electrode (see col. 12, lines 58-64 and figure 7), hence the active electrode is activated. Furthermore, Hill et al. also teaches that reference electrode is also screen printed on the substrate (see col. 12, lines 40-43). Therefore, it would be obvious to person of ordinary skill in the art to screen print both reference electrode and biological molecules in the same work step.

Furthermore, the selection of any order of performing process steps is prima facie obvious in the absence of new or unexpected results. See *In re Burhans*, 154 F.2d 690, 69 USPQ 330 (CCPA 1946) (see MPEP § 2144.04). Moreover, the use of a known technique to improve similar devices (methods or products) in the same way is likely to be obvious. See *KSR International Co. v. Teleflex Inc.*, 550 U.S. __,__, 82 USPQ2d 1385, 1395 – 97 (2007) (see MPEP § 2143, C.).

Advantage to method of Hill et al. is that it is amenable to high volume automation and is of high reproducibility (see col. 12, lines 49-50).

Furthermore, claims 30-32 is/are considered product-by-process claim wherein the reference electrode is formed by printing silver material as metal on the substrate and biological material are applied by printing the sensor array. The cited prior art teaches all of the positively recited structure of the claimed apparatus or product. The determination of patentability is based upon the apparatus structure itself. The patentability of a product or apparatus does not depend on its method of production or formation. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (see MPEP § 2113).

Therefore it would be obvious to person of ordinary skill in the art at the time of invention to incorporate the method of Hill et al. with the method of Madou et al. because advantage of such a method that it is amenable to high volume automation and is of high reproducibility.

Response to Arguments

Applicant's arguments filed 9/08/2009 have been fully considered but they are not persuasive.

Regarding claim 13, applicant argues on pages 8 and 9 that Madou in view of Hill does not teach applying biological molecules and silver material on the substrate in the same work step.

Examiner respectfully disagrees with applicant's argument. Applicant describe the process of printing of silver core of reference electrode and capture molecules by same printing technology and in the same work step (see paragraph 0058). Thus, the silver core and biological molecules are being screen printed in two steps. As mentioned above, Hill et al. teaches the method wherein the silver material and enzyme layer is screen printed in two steps by the same printing technology. Therefore, it would be obvious to screen print both the silver material and enzyme layer in the same work step i.e. screen print the silver material followed by enzyme layer or vice versa before moving onto the next work step. In doing so one can screen print both the silver material and the enzyme layer at the same time and thus expediting the manufacturing process.

Regarding claim 21, applicant argues that Madou in view of Yoshikawa does not teach printing silver salt material on the substrate. However, as described above in rejection of clam 21, Examiner uses Madou in view of Yoshikawa and Hill to teach that

silver salt material being printed on the substrate (see Hill et al. col. 12, lines 40-64). Examiner acknowledges that Yoshikawa reference is a non-analogous art. However, Yoshikawa is used only to teach that silver salt material can under go silver mirror reaction to form silver layer which is disposed on a substrate. Yoshikawa does not teach that silver salt is deposited by printing, however, Hill teaches that silver salt can be deposit by screen printing. Therefore it would be obvious to deposit silver salt by printing.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GURPREET KAUR whose telephone number is (571)270-7895. The examiner can normally be reached on Monday-Friday (Alternate Friday Off), 8:00-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/
Supervisory Patent Examiner, Art Unit 1753

/G. K./
Examiner, Art Unit 1795
12/17/09